REMARKS

1. Introduction

The Office Action dated September 6, 2007 and cited references have been considered. Claims 1-12 have been examined and claims 13-28 have been withdrawn. Reconsideration and allowance of the application are respectfully requested.

2. Restriction Requirement

In paragraphs 1-8 of the Office Action, the Examiner has set forth a restriction requirement identifying groups I, II, III and IV. Applicant hereby confirms the election with traverse of group I which includes claims 1-12. Applicant respectfully submits, however, that search and examination of all the claims in the application can be made without serious burden to the Examiner and therefore under MPEP § 803 the Examiner must examine all the claims on the merits. Accordingly, Applicant respectfully requests withdrawal of the restriction requirement.

3. Objections to the Specification

In paragraphs 9-10 of the Office Action, the Examiner has objected to the specification for various informalities. Applicant has amended the specification to address most of the Examiner's objections. However, there are a few objections that Applicant respectfully traverses. In particular, Applicant respectfully submits that: (a) disclosure of both vertical and horizontal orientation of the cyclotron are simply alternative embodiments and not contradictory; and (b) "^{15}O water" is correct.

Accordingly, reconsideration and withdrawal of the objections to the specification are respectfully requested.

4. Objections to the Drawings

On page 8 of the Office Action, the Examiner has objected the drawings as failing to comply with 37 CFR 1.84(p)(4) because reference characters "104" and "135" have both been used to designate a computer. Paragraphs [0016] and [0032] of the specification and Figure 1 of the drawings have been amended to address the Examiner's objection. A replacement drawing sheet for Figure 1 is submitted herewith. Accordingly, reconsideration and withdrawal of the objection to the drawings are respectfully requested.

5. Claim Rejections

On page 10 of the Office Action, claims 1-3 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,037,602 to Dabiri et al. ("Dabiri") in view of U.S. Patent No. 6,445,146 to Bergstrom et al. ("Bergstrom") and in further view of U.S. Patent No. 4,943,781 to Wilson et al. ("Wilson"). This rejection is respectfully traversed.

Dabiri discloses a radioisotope production facility for use with Positron Emission Tomography (PET). The radioisotopes are produced by irradiating a selected target material with a high energy $^{3}He^{++}$ beam accelerated in a radio frequency quadruple (RFQ) linear accelerator. *See* Dabiri Abstract. The accelerated $^{3}He^{++}$ beam is then directed to a conventional, non-enriched target material where the four primary radionuclides of interest to PET systems are produced. *See* Dabiri col. 3, lines 8-16.

Claim 1 recites, among other things, transporting a cyclotron to a site; and enclosing the cyclotron inside the manufacturing facility. The Examiner acknowledges on page 10 of the Office Action that Dabiri does not disclose a cyclotron. The Examiner cites Bergstrom and Wilson to remedy this admitted deficiency. The Office Action alleges that Bergstrom discloses a compact cyclotron suitable for installation in a PET isotope production facility with limited space. Also, the Office Action alleges that Wilson discloses a "highly transportable" cyclotron with reduced size and weight due to lack of an iron yoke for the magnet. The Office Action concludes that a person of ordinary skill in the art would recognize from the teachings of Dabiri that cyclotrons are more typically used in PET isotope production systems over RFQ linear accelerators, when Dabiri is modified in view of Bergstrom and Wilson; and one would have been motivated to make such modifications because the space limitations presented by an ordinary cyclotron in a transportable facility could be overcome by a more compact cyclotron. *See* Office Action pp. 10-11.

Applicant strongly disagrees. Applicant respectfully submits that Dabiri, Bergstrom and Wilson teach away from each other in very significant ways. In particular, Dabiri clearly teaches away from using a cyclotron by highlighting numerous disadvantages of the cyclotron:

> *Because of the sheer size, mass and expense of building and operating just the cyclotron (which is only one element of a PET system), there are relatively few PET facilities available throughout the world.* (At present, it is estimated that there are only about 20 PET facilities in the United States, and about 60-70 worldwide.) Only the largest hospitals are able to afford, support and staff such systems. Thus, the benefits of PET remain available to relatively few. What is needed therefore is a PET system that is more affordable and accessible to a larger number of patients and doctors. Dabiri at col. 2, lines 12-24.

> *There are numerous disadvantages of existing low energy cyclotron-based PET systems. For example*, some of the radionuclides are produced using a proton beam, while others are produced using a deuteron beam, therefore *some beam switching apparatus is*

> *required.* While such beam switching apparatus is well known in the art, it *adds to the complexity and expense of the system. Further, large amounts of power are required* for such systems to operate (e.g., the proton/deuteron cyclotron typically requires 100 kW of power to operate). *Also, such systems require enriched target materials* if the desired radionuclides are to be efficiently produced by the proton/deuteron beam. *Such enriched target materials are not readily available, and are costly to produce. Still further,* due to the inherent elliptical cross sectional shape of the proton/deuteron beam, *the efficient utilization of the beam in a circular target chamber is made more difficult. Moreover,* due to the secondary neutrons that are naturally produced from the proton/deuteron irradiation process, *thick shields must be built around the target area to confine such neutron radiation.* It is not uncommon, for example, for the target chamber of such systems to be surrounded by concrete walls that are a minimum of four feet thick. *This shielding, coupled with the mass and weight associated with the other elements of the system, particularly the cyclotron, results in a system that weighs on the order of 300 tons.* Such heavy systems can only be installed on a ground or basement floor, thereby severely restricting those facilities where a cyclotron-based PET system could be installed. *All of the above factors combine to make the proton/deuteron cyclotron-based PET systems very expensive to build, operate and maintain.* Dabiri at col. 2, lines 24-58 (emphasis added).

Dabiri then goes on to explain the advantages of its system that uses a Radio Frequency Quadrupole (RFQ) accelerator instead of a cyclotron:

> The present invention is directed to a relatively inexpensive PET system that is easy to operate and maintain, and that produces all four of the radionuclides of interest to PET applications. Significantly, the system described herein *does not require a cyclotron* to generate a proton/deuteron beam. *Rather, the PET system of the present invention makes use of a readily available ion source to produce a $^{3}He^{++}$ beam that is accelerated to around 8 MeV using a Radio Frequency Quadrupole ("RFQ") accelerator.* This accelerated $^{3}He^{++}$ beam is then directed to a conventional, non-enriched target material(s) whereat the four primary radionuclides of interest to PET systems, ^{18}F, ^{13}N, ^{15}O, and ^{11}C, are efficiently produced. *Advantageously, the RFQ accelerator is a small, light-weight device and requires significantly less operating power than does the cyclotron.* The RFQ advantageously accelerates ions to a prescribed velocity. The RFQ is thus ideal for accelerating multiply charged ions with masses greater than a single proton mass. This characteristic of the RFQ, *in combination with the benefits of using $^{3}He^{++}$, rather than protons or deuterons as described below,* renders use of a ^{3}He RFQ as an advantageous and novel technique for producing radioisotopes for PET. Dabiri at col. 3, lines 3-26 (emphasis added).

* * *

Further, the neutron-poor nature of the reaction resulting from a $^{3}He^{++}$ bombardment of

> the target material *significantly reduces the amount of shielding that is required* around the target chamber. *Moreover, the generally circular cross section of the $^3He^{++}$ beam allows it to interact with the conventional circular cross-section target material in a more efficient manner than is possible with the elliptical cross-sectional shaped proton/deuteron beam of the cyclotron-based system of the prior art. The reduced shielding requirements, coupled with the small RFQ accelerator and the relatively low power requirements thereof, as well as the efficient use of the target material, makes possible a PET system that not only efficiently generates the needed radionuclides for PET applications, but that also is small, light-weight, affordable, and possibly transportable.* Hence, the system can either be readily installed in or possibly transported to the hospitals and other medical facilities where it is needed, thereby making the benefits of PET available to a much larger segment of the world's population. Dabiri at col. 3, lines 27-46 (emphasis added).
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> Another feature of the present invention is to provide such a system that *operates on roughly 1/5 of the operating power required by the cyclotron-based PET systems* of the prior art. Dabiri at col. 4, lines 17-20 (emphasis added).
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> A further feature of the invention is to provide a PET system that *occupies only about 1/3 of the floor space that is occupied by the cyclotron-based PET systems* of the prior art, and that weighs only about 1/10 of what such prior art cyclotron-based systems typically weigh. Dabiri at col. 4, lines 21-25 (emphasis added).

Based on these numerous statements in Dabiri emphasizing the advantages of an RFQ accelerator over a cyclotron, Applicant submits that *it would not have been at all obvious to modify the Dabiri system to replace the RFQ accelerator with a cyclotron.* The whole point of the Dabiri patent is to eliminate the cyclotron. Applicant respectfully submits that the claim rejection is improperly based on hindsight, as Dabiri in fact strongly teaches away from the use of a cyclotron for many reasons.

Furthermore, even the cyclotron disclosed by Bergstrom and the cyclotron disclosed by Wilson are distinct and teach away from each other. Specifically, Wilson discloses a cyclotron including an "axial magnetic field provided by *yokeless* means in the form of a superconducting

magnet 29 having a set of superconducting magnet coils 21 through to 24 which are housed in a cryostat 25." *See* Wilson column 2, lines 53-56; *See also* Wilson at col. 1, lines 57-59 ("The present invention provides a design of cyclotron using a superconducting magnet *which has no iron yoke*."). In contrast, Bergstrom discloses a cyclotron including an "electromagnetic field created between the magnet poles 1 and 2 by means of coils arranged on a yoke." *See* Bergstrom col. 4, lines 14-19. Therefore, Wilson teaches away from using a yoke for generating a magnetic field as disclosed by Bergstrom.

In short, Applicant respectfully submits that the Office Action improperly relies to a large degree on hindsight to piece together the limitations recited in claim 1. Therefore, the Office Action fails to establish a prima facie case of obviousness to combine Dabiri, Bergstrom and Wilson. Accordingly, reconsideration and withdrawal of the rejection of claim 1 set forth on page 10 of the Office Action is respectfully requested. The dependent claims are allowable for at least the same reasons that claim 1 is allowable.

The remaining claim rejections set forth on pages 11-15 of the Office Action all rely on the combination of Dabiri, Bergstrom and Wilson, in addition to other secondary references. Accordingly, the arguments presented above are equally applicable to the remaining claim rejections. Applicant therefore respectfully submits that these claim rejections are improper and requests reconsideration and withdrawal of these rejections.

6. Conclusion

In view of the above remarks, Applicant respectfully submits that the present application is in condition for allowance, and notice to that effect is respectfully solicited. If there are any

questions regarding this Amendment or the application in general, the Examiner is encouraged to contact the undersigned to expedite prosecution.

Submitted herewith is a petition for a 1-month extension of time including an authorization to charge the required petition fee. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0206, and please credit any excess fees to the same deposit account.

Respectfully submitted,

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